# In the United States Court of Federal Claims

**OFFICE OF SPECIAL MASTERS**

Filed: October 31, 2019

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| MARY ORLOSKI, | * | No. 17-936V |
| Petitioner, | * | Special Master Sanders |
| v. | * | |
| SECRETARY OF HEALTH AND HUMAN SERVICES, | * | Ruling on the Record; Influenza ("flu") Vaccine; Tetanus-diphtheria-acellular-pertussis ("Tdap") Vaccine; Acute Disseminated Encephalomyelitis ("ADEM") |
| Respondent. | * | |

Verne E. Paradie, Jr., Paradie, Sherman, et al., Lewiston, ME, for Petitioner.
Robert P. Coleman, III, United States Department of Justice, Washington, DC, for Respondent.

## DECISION[1]

On July 13, 2017, Mary Orloski ("Petitioner") filed a petition for compensation in the National Vaccine Injury Compensation Program ("the Program").[2] Pet. 1, ECF No. 1. Petitioner alleged that the influenza ("flu") vaccine she received on October 23, 2014, and the tetanus-diphtheria-acellular-pertussis ("Tdap") vaccine she received on November 18, 2015, caused her to develop acute disseminated encephalomyelitis ("ADEM").[3] *Id.* The information in the record, however, does not show entitlement to an award under the Program.

### I. Procedural History

Petitioner filed her petition along with one exhibit consisting of medical records on July

[1] This decision shall be posted on the website of the United States Court of Federal Claims, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, § 205, 116 Stat. 2899, 2913 (codified as amended at 44 U.S.C. § 3501 note (2012)). As provided by Vaccine Rule 18(b), each party has 14 days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b).

[2] National Childhood Vaccine Injury Act of 1986, Pub L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

[3] Acute disseminated encephalomyelitis is defined as "an acute or subacute encephalomyelitis or myelitis characterized by perivascular lymphocyte and mononuclear cell infiltration and demyelination . . . . It is believed to be a manifestation of an autoimmune attack on the myelin of the central nervous system." *Dorland's Illustrated Medical Dictionary* 613 (32nd ed. 2012) [hereinafter "*Dorland's*"].

13, 2017. *See* Pet. at 1; Pet'r's Ex. 1, ECF Nos. 1-1, 1-2, 1-3, 1-4.[4] Petitioner filed her first statement of completion on October 10, 2017. ECF No. 10.

Respondent filed his Rule 4(c) report on April 23, 2018, in which he argued that the petition should be dismissed because Petitioner did not present "a reliable theory of causation, logical sequence of cause and effect, or appropriate temporal relationship." Resp't's Report at 9, ECF No. 22. I ordered Petitioner to file an expert report and supporting medical literature by July 16, 2018. *See* Non-PDF Order, docketed June 6, 2018.

On July 16, 2018, Petitioner filed one exhibit consisting of seven pages of medical records from Dr. Alexandra Degenhardt, a neurologist. Pet'r,'s Ex. 3, ECF No. 29. Petitioner did not file a formal expert report or supporting medical literature by the July 16, 2018 deadline. *See* docket. On July 17, 2018, Chambers contacted Petitioner via email regarding her missed deadline. *See* Informal Comm., docketed July 17, 2018. Petitioner replied in a status report that "[i]f [Petitioner's Exhibit 3 was] insufficient and the Court require[d] something more formal . . . Petitioner would request additional time to inquire of Dr. Degenhardt." ECF No. 30. I ordered Respondent to file a status report by August 16, 2018, indicating whether, based on Petitioner's Exhibit 3, his position as to litigation or settlement had changed. Non-PDF Order, docketed July 17, 2018.

On August 15, 2018, Respondent filed a status report indicating that he "intend[ed] to continue to contest entitlement in this case." ECF No. 31. I then ordered Petitioner to file a formal expert report and supporting medical literature by October 22, 2018. ECF No. 32. The order required Petitioner to submit an expert report that specifically included discussions of the expert's qualifications, pertinent facts from Petitioner's medical records, background on Petitioner's alleged disease or injury, a theory of causation, and any non-vaccine potential causes. *Id.* On October 2, 2018, Petitioner filed an expert report from Dr. Degenhardt. Pet'r's Ex. 4, ECF No. 33. The report consisted of one page of text in which Dr. Degenhardt stated "there is a clear temporal relationship between the vaccinations [administered to Petitioner] and [Petitioner's] symptoms, so the most consistent diagnosis is ADEM." *Id.* at 1. Dr. Degenhardt did not include her qualifications, an overview of ADEM, a synopsis of pertinent medical facts, nor a causation theory of any kind. *See id.* Petitioner did not file any pieces of supporting medical literature.

On October 15, 2018, I again ordered Petitioner to file a formal expert report by no later than November 14, 2018. ECF No. 34. In the order, I noted that Petitioner's Exhibit 4 "d[id] not adequately address any of the topics listed in the August 21, 2018 [o]rder." *Id.* Petitioner filed a status report on October 17, 2018, wherein she stated that she "ha[d] chosen to submit medical opinions and records from her treating physician, which state[d] that the logical sequence of cause and effect show[ed] that the vaccination was the most likely reason for Petitioner's injuries, and which Petitioner maintains supports her claim for compensation." *Id.* at 2. Petitioner also indicated that she "d[id] not anticipate submitting any further reports from non-treating 'experts.'" *Id.*

[4] Petitioner re-filed Exhibits 1(a)–(f) on February 19, 2018, because the original filings "were not properly labeled and numbered . . . ." ECF No. 15 at 1. Petitioner filed a motion to strike the original exhibits on February 21, 2019, *see* ECF No. 16, which I granted, ECF No. 17.

On October 18, 2018, Chambers contacted Respondent to inquire how he wished to proceed in light of Petitioner's status report. *See* Informal Comm., docketed Oct. 18, 2018. Respondent indicated that he did not intend to file a responsive expert report. *Id.*

I ordered the parties to appear for a status conference on November 13, 2018. *See* Non-PDF Order, docketed Nov. 7, 2018. During the status conference, Petitioner clarified her position regarding how the case should proceed and requested additional time to supplement the record with medical literature and other evidence related to her causation theory. ECF No. 36. I ordered Petitioner to file any such evidence by December 13, 2018. *Id.*

On December 12, 2018, Petitioner filed the present motion for ruling on the record, ECF No. 37, along with five exhibits consisting of additional medical records, two pieces of medical literature, and an affidavit, Pet'r's Ex. 5–10, ECF Nos. 38-1–38-6; ECF No. 38-7. On December 16, 2018, Respondent filed a status report "request[ing an] opportunity to respond to [P]etitioner's filings with an expert report[.]" ECF No. 39. Respondent filed an expert report from Dr. Subramaniam Sriram and one piece of medical literature on March 27, 2019. Resp't's Ex. A, C, ECF Nos. 43-1, 43-3. Respondent did not file a direct response to Petitioner's motion, although Respondent's expert report encompassed many of the arguments commonly found in a formal response.

On April 3, 2019, Chambers contacted Petitioner to inquire whether she intended to file a responsive expert report. *See* Informal Comm., docketed Apr. 3, 2019. Petitioner responded that she did not anticipate filing an additional expert report but requested twenty-one days to file a response. I ordered Petitioner to file a response by April 24, 2019. Non-PDF Order, docketed Apr. 3, 2019. Petitioner filed a reply brief on April 24, 2019, ECF No. 44,[5] along with a second affidavit and two photographs purporting to show an injection site reaction. ECF No. 44; Pet'r's Exs. 11–12, ECF Nos. 45-2–45-3; ECF No. 45-1.

Neither party has filed any additional evidence. This matter is now ripe for adjudication.

## II. Factual Background

### A. Relevant Medical History

Petitioner worked as a registered nurse and a certified clinical document specialist prior to receiving the vaccinations at issue in this case. Pet'r's Aff. ¶ 2(i), ECF No. 38-7. Petitioner received the flu vaccine at issue in this case on October 23, 2014, at approximately 7:00 AM. Pet'r's Ex. 1(c) at 37. At approximately 8:30 AM that morning, Petitioner began experiencing visual disturbances where she "felt that she could not see out of both eyes." *Id.* These visual disturbances completely resolved after approximately twenty minutes. *Id.* At approximately 9:50 AM, Petitioner presented to the emergency room and saw Rob Boudewijn, PA-C, for treatment related to these disturbances. *Id.* Petitioner told PA-C Boudewijn that she "[was] quite convinced

[5] In her reply, Petitioner mostly reiterated her arguments contained in her original motion, aside from citing to an additional Vaccine Program case which she argues "is nearly identical" to hers. Pet'r's Reply at 14; *see also Mondello v. Sec'y of Health and Human Servs.*, No. 15-972V, 2018 WL 947449 (Fed. Cl. Spec. Mstr. Jan. 24, 2018).

that [the visual disturbances were] an allergic reaction to the flu shot." *Id.* However, PA-C Boudewijn disagreed and "had a long discussion with [Petitioner] that [his] suspicion for [the visual disturbances] being an allergic reaction due to the flu shot [was] extremely low." *Id.* at 38. PA-C Boudewijn released Petitioner with directions to follow-up with her primary care physician ("PCP"). *Id.*

On December 5, 2014, Petitioner presented to her PCP, Charles Burger, M.D., to "discuss her [post-traumatic stress disorder ("PTSD")] and [the effect] set off by her reaction to the flu vac[cination]." Pet'r's Ex. 1(f) at 3. Petitioner noted that her PTSD had been life-long and related to issues within her family. *Id.* Dr. Burger arranged a psychiatric referral for Petitioner and discussed medication options but did not prescribe any due to Petitioner's "fear of . . . [selective serotonin reuptake inhibitors]." *Id.* On January 22, 2015, Petitioner presented to David Breer, M.D., a psychiatrist. Pet'r's Ex. 7 at 1. Petitioner "denie[d] any significant worsening of her symptoms" resulting from her long-standing anxiety and depression but "describe[d] significant recent physical symptoms[,] which ha[d] contributed to [Petitioner's] feelings of anxiety and being overwhelmed by stress." *Id.* Petitioner reported a variety of symptoms, including "frequent episodic severe head pain when lying down associated with facial twitching, apnea, stuttering, difficulty breathing, and noise in her ears . . . ." *Id.* Petitioner also reported a history of "ocular respiratory reaction to [the] flu vaccine" and "numbness and tingling of hands and feet with ciprofloxacin.[6]" *Id.* Dr. Breer assessed Petitioner with depression and anxiety disorder and scheduled a follow-up appointment to continue treatment. *Id.* at 3.

Petitioner's next relevant medical appointment occurred on November 11, 2015, when she presented to a new PCP, Dr. David Preston, M.D., to establish care. Pet'r's Ex. 1(a) at 71. Petitioner voiced four main concerns to Dr. Preston: atrial arrhythmia, arthritis, poor sleep possibly related to anxiety, and clinical lynch syndrome.[7] *Id.* at 71–72. An examination revealed that Petitioner's range of motion ("ROM") in her neck was "limited." *Id.* at 72. Petitioner did not mention any neurological complaints. *See id.* During this appointment, Petitioner received the Tdap vaccine at issue in this case. *Id.* at 73. Based on Petitioner's limited neck ROM, Dr. Preston concluded that she "ha[d] a degenerative [neck] disease[.]" He referred Petitioner to physical therapy ("PT") and discussed treatment options for her other concerns. *Id.* The medical record does not contain any mention of Petitioner's alleged reaction to the flu vaccine.

Petitioner presented for her first PT session on December 10, 2015. Pet'r's Ex. 1(b) at 40. Petitioner reported that her neck pain had begun over five years prior without trauma. *Id.* She attended eight sessions over the next two months and was discharged from PT on February 5, 2016. *Id.* at 39. On February 23, 2016, Petitioner presented to Dr. Preston for a follow-up and stated that PT had been "quite helpful for her chronic neck pain." *Id.* at 67–68. However, Petitioner reported a new problem—"intermittent tingling and numbness of the toes of both feet." Pet'r's Ex. 1(a) at 68. Petitioner also reported experiencing, over a longer, undefined period of time, tingling and numbness in her hands, although "she [could not] remember which fingers [were] affected but it seem[d] to be both palms." *Id.* Dr. Preston assessed the tingling in Petitioner's toes and feet as "consistent with an early sensory peripheral neuropathy," and the

[6] Ciprofloxacin is "a fluoroquinolone antibacterial effective against many gram-positive and gram-negative bacteria . . . ." *Dorland's* at 362.

[7] Lynch syndrome is "hereditary nonpolyposis colorectal cancer." *Dorland's* at 1838.

tingling in Petitioner's hands as "most consistent with carpal tunnel syndrome."[8] *Id.* at 69. Petitioner declined referral to a neurologist and specific treatment for the tingling in her feet. *Id.* She did agree to try wrist splints at night to attempt to control the tingling in her hands. *Id.*

Petitioner retuned to Dr. Preston on March 2, 2016, for a follow-up for her peripheral neuropathy. *Id.* at 64. Petitioner stated that her symptoms had worsened since her last visit and now "involve[d] the whole plantar surface of the foot and even going up a little bit on the ankle bilaterally." *Id.* Petitioner stated, "that she fe[lt] this may be an autoimmune process, possibly related to the [Tdap] shot that [she received in] November." *Id.* Dr. Preston noted that because Petitioner's symptoms were "fluctuating [in] nature" and involving her hands "simultaneously with the feet[,]" the totality of her symptoms "would possibly argue against a peripheral neuropathy and more toward[] an anxiety reaction." *Id.* at 66. Dr. Preston referred Petitioner for a neurology consult with Robert Stein, M.D. *Id.*

Petitioner presented to Dr. Stein on April 20, 2016. Pet'r's Ex. 5 at 1. Petitioner reported that she "has had headaches on a daily basis for over 15 years." *Id.* Petitioner also reported that "[o]ne and a half hours after receiving [a] flu shot [in October 2014,] she developed shortness of breath and blurring of her eye site [(sic),]" which "improved within 2-1/2 hours." *Id.* Petitioner stated that "[s]he made the diagnosis of oculorespiratory syndrome."[9] *Id.* Petitioner also stated that "she developed tingling sensation in her feet and hands and arms and legs[,]" and for the first time, stated that these symptoms developed "[w]ithin the next several days [after receiving the flu vaccine.]" *Id.* *Id.* Petitioner noted that this tingling "persisted for [six] weeks until [it] nearly resolved" and left Petitioner "with a residual tingling in the feet[,] which was constant[,] and episodic paresthesias[10] in the hands." *Id.* Petitioner then discussed the Tdap vaccination she received in November 2015. She stated that "[s]oon after this injection, she noted the paresthesias and a burning sensation intensifying in her feet[,]" which eventually "[s]pread up all [four] of her extremities." *Id.* Petitioner reported that "[s]ince that time, she feels these paresthesias have become more intense and somewhat wider spread in her extremities." *Id.* Petitioner also complained of weakness in her hands, difficulty swallowing, blurry vision in both eyes, a tremor at rest in her right hand, and intermittent fatigue. *Id.* at 2. Dr. Stein assessed Petitioner with paresthesias, which he "suspect[ed] . . . represent[ed] most likely [a] peripheral neuropathic dysfunction." *Id.* at 4. Dr. Stein clarified that Petitioner "appear[ed] to have a sensory length-dependent small fiber neuropathy." *Id.* Dr. Stein also assessed Petitioner with "migraine-like events" and right hemifacial spasm. He noted that "[multiple sclerosis ("MS") [11]] as the etiology

[8] Carpal tunnel syndrome is "an entrapment neuropathy characterized by pain and burning or tingling paresthesias in the fingers and hand, sometimes extending to the elbow. Symptoms result from compression of the median nerve in the carpal tunnel." *Dorland's* at 1824.

[9] Oculorespiratory syndrome is "a usually transient syndrome of bilateral red eyes and upper respiratory symptoms, including cough, wheezing, chest discomfort, sore throat, and occasionally facial edema, following [flu] vaccination." *Steadman's Medical Dictionar*y 1907 (28th ed. 2006).

[10] Paresthesia is defined as "an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus." *Dorland's* at 1383.

[11] Multiple sclerosis is "a disease in which there are foci of demyelination throughout the white matter of the central nervous system, sometimes extending into the grey matter . . . . The course of the disease is usually prolonged, so that the term *multiple* also refers to the remissions and relapses that occur over the period of many years." *Dorland's* at 1680. For a definition of central nervous system, see *infra* note 13.

would seem unlikely although the syndrome did start at age of 44." *Id.*

On July 14, 2016, Petitioner presented to Dr. Degenhardt, a neurologist, for a consultation. Pet'r's Ex. 1(b) at 58. Dr. Degenhardt reviewed Petitioner's history of symptoms and noted that "within [forty-eight] hours" after Petitioner received the flu vaccine in October of 2014, Petitioner developed "tingling and numbness in the arms and legs . . . [, which] rose up the legs to the knees and elbows." *Id.* This tingling and numbness "took another [six] weeks to resolve." *Id.* Dr. Degenhardt also noted that "within [twenty-four] hours" after Petitioner received the Tdap vaccine in November of 2015, "she felt ill again" and developed "tingling[,] . . . numbness[,] . . . [and] burning in [her] arms and legs." *Id.*

Dr. Degenhardt reviewed an MRI of Petitioner's brain and noted "mild to moderate round (slightly larger than punctuate) T2 hyperintensities[,] which are nonspecific. No confluent lesions." *Id.* at 60. After a physical examination, Dr. Degenhardt assessed Petitioner as having "[n]oninfectious [ADEM]." *Id.* at 61. Dr. Degenhardt stated "[a]lthough there is very little on [Petitioner's] brain MRI to diagnose ADEM, the mild cognitive and visual changes with the presentation[] suggests some degree of central [nervous system ("CNS")][12] as well as peripheral[13] syndrome. The peripheral syndrome is most consistent with a [Guillain-Barré syndrome ("GBS")[14]] like presentation following two vaccines[.]" *Id.* at 61. Dr. Degenhardt ruled out chronic inflammatory demyelinating polyneuropathy ("CIDP")[15] because "after so many months, [Petitioner's condition] appears to be a stuttering chronic autoimmune condition." *Id.* Dr. Degenhardt recommended treatment with either "[o]ne day of IVIG or [three] days of lower dose steroids" and told Petitioner to "avoid[] these specific vaccines." *Id.*

On August 5, 2016, Petitioner returned to Dr. Preston for a follow-up. Pet'r's Ex.1(a) at 61. After reviewing Petitioner's encounter with Dr. Degenhardt, Dr. Preston stated he "believe[d] much of [Petitioner's] symptoms could be attributed to anxiety and panic disorder, including paresthesias, which is fairly classic for hyperventilation. Nonetheless, [he] would defer to Dr Degenhardt for her neurological diagnoses." *Id.* at 62.

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[12] The central nervous system is "the part of the nervous system consisting of the brain and spinal cord." *Dorland's* at 1859. When both the brain and spinal cord become inflamed, it is called "encephalomyelitis." *Id.* at 613. ADEM and MS are types of encephalomyelitis. *See id; see also id.* at 1680.

[13] Peripheral nerves are "any nerve outside the [CNS]." *Dorland's* at 1253. A peripheral neuropathy (also known as a "polyneuropathy") is a "neuropathy of several peripheral nerves simultaneously . . . ." *Id.* at 1491. Both CIDP and GBS are considered peripheral neuropathies. *See id.*

[14] Guillain-Barré syndrome is a "rapidly progressive ascending motor neuron paralysis of unknown etiology, frequently seen after an enteric or respiratory infection. . . . It begins with paresthesias of the feet, followed by flaccid paralysis of the entire lower limbs, ascending to the trunk, upper limbs, and face . . . ." *Dorland's* at 1832.

[15] Chronic inflammatory demyelinating polyneuropathy is "a slowly progressive, autoimmune type of demyelinating polyneuropathy characterized by progressive weakness and impaired sensory function in the limbs and enlargement of the peripheral nerves, usually with elevated protein in the cerebrospinal fluid. It occurs most commonly in young adults, particularly males, and is related to [GBS]. Presenting symptoms often include tingling or numbness in the digits, weakness of the limbs, hyporeflexia or areflexia, fatigue, and abnormal sensations." *Dorland's* at 1491.

Petitioner underwent an MRI of her cervical spine on September 9, 2016. *Id.* at 37. The MRI revealed "mild multilevel cervical spondylosis[16] most pronounced at C4-5 but no appreciable stenosis,[17]" and "no intrinsic cord abnormality . . . ." *Id.* Petitioner also underwent an EMG on this date. Pet'r's Ex. 1(c) at 47. The results revealed "an essentially normal study." *Id.*

On September 12, 2016, Petitioner presented to Dr. Degenhardt for a follow-up. Pet'r's Ex. 1(a) at 28. Petitioner complained of "pressure on the front of her head[] and often on the top of her head . . . [, which was] exacerbated by computers and driving . . . [and could] also be associated with odors." *Id.* Petitioner also complained of daily headaches, which had occurred for over five years. *Id.* Dr. Degenhardt noted that these headaches "[were] complicating her presentation and c[ould] produce cognitive issues." *Id.* at 30. Regarding Petitioner's "[p]ossible ADEM – like reaction to vaccination," Dr. Degenhardt noted that it was "[v]ery atypical to have prolonged associated symptoms[;] however, [Petitioner] ha[d] a mildly elevated protein[,] which [was] abnormal and [could] indicate[] inflammation." *Id.* Therefore, Dr. Degenhardt ordered "[t]esting for other autoimmune antibody mediated encephalopathies with [the] Mayo Clinic." *Id.* Petitioner underwent a battery of tests for different autoantibodies and proteins, all of which returned negative. Pet'r's Ex. 1(a) at 5; Pet'r's Ex. 1(d) at 68–72. Of note, an autoimmune encephalopathy evaluation found "[n]o informative autoantibodies . . . ." *Id.* at 69.

On December 5, 2016, Petitioner returned to Dr. Degenhardt for a follow-up. *Id.* at 20. Dr. Degenhardt definitively diagnosed Petitioner with ADEM because "[n]europsychology testing[18] confirm[ed] . . . a CNS process[,]" and Petitioner "ha[d] a mildly elevated protein[,] which [was] abnormal and [could] indicate[] inflammation. The timing also coincide[d] with [Petitioner's] history and presentation." *Id.* at 22. Dr. Degenhardt stated that although "[t]here is an overlap with ADEM and GBS, and ADEM and MS[,] . . . the diagnosis is most consistent with ADEM currently." *Id.* Dr. Degenhardt also noted that Petitioner was experiencing a "rare and . . . atypical presentation [of ADEM]." *Id.*

Petitioner presented to Haatem Reda, M.D., at the Department of Neurology at Massachusetts General Hospital on January 12, 2017, for a second opinion regarding her ADEM diagnosis. Pet'r's Ex. 1(b) at 43. After reviewing Petitioner's symptoms and MRI results from the years 2008, 2009, and 2016, Dr. Reda stated "if [Petitioner] does have [a CNS] demyelinating disease, it predates the vaccination in 2014 and the symptoms she developed at that time. The differential diagnosis still includes prior [ADEM], though [MS] would be more likely on

[16] Spondylosis is "1. [stiffening] of a vertebral joint[; and] 2. Degenerative spinal changes due to osteoarthritis." *Dorland's* at 1754.

[17] Spinal stenosis is "narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine caused by encroachment of bone upon the space; symptoms are caused by compression of the cauda equina and include pain, paresthesias, and neurogenic claudication." *Dorland's* at 1770.

[18] Petitioner did not provide records of this testing. However, the National Institute of Health defines a neuropsychological assessment as "a performance-based method to assess cognitive functioning . . . used to examine the cognitive consequences of brain damage, brain disease, and severe mental illness." Philip D. Harvey, *Clinical Applications of Neuropsychological Assessment*, 14(1) DIALOGUES CLIN. NEUROSCI. 91, 91 (2012) (filed as Court's Ex. A, ECF No. 46-1).

neuroimaging grounds." *Id.* at 45; *see also* Not. of Filing on Compact Disk, ECF No. 40. Dr. Reda concluded "[a]t this point, given clinical and radiographic stability, I would not recommend initiating empiric immunomodulatory therapy, unless [Petitioner] develops new symptoms, signs, and/or imaging findings suggestive of CNS inflammatory disease." *Id.*

On February 16, 2017, Petitioner returned to Dr. Degenhardt for an "MS follow-up." Pet'r's Ex. 1(a) at 7. Petitioner reported "feeling a little better." *Id.* Despite Dr. Reda's conclusion that MS was the more likely diagnosis, Dr. Degenhardt reiterated her conclusion that Petitioner's "[cerebrospinal fluid ("CSF")[19]] findings [were] more consistent with ADEM than with MS." *Id.* at 11.

Petitioner had another follow-up appointment with Dr. Degenhardt on May 4, 2017. *Id.* at 2. Petitioner reported being "around 85% close to [her] baseline." *Id.* Dr. Degenhardt restated that "[n]europsychology testing confirms findings that support a CNS process. There continues to be a mild processing delay with recall and learning since the ADEM. With improved rest, reduced stress, and improved sleep, [Petitioner] appears to be improving and functioning close to her prior level." *Id.*

The last medical records Petitioner submitted are from a June 5, 2018 follow up with Dr. Degenhardt. Pet'r's Ex. 3 at 1. Petitioner reported experiencing "[t]ingling and burning on [her] left leg" and noted that that leg "will drag." *Id.* She also reported experiencing "tingling in both palms[,]" and Dr. Degenhardt reaffirmed her diagnosis of ADEM. *Id.* Petitioner also noted "an occasional skin reaction in the region of her prior vaccin[ations]." *Id.* at 6. Dr. Degenhardt reviewed pictures, which Petitioner stated depicted her Tdap vaccination site from November 18, 2015, and the same site sometime in July of 2016. *Id.* Dr. Degenhardt noted that this was an "unusual" reaction. *Id.* Dr. Degenhardt opined that "perhaps . . . [it was] a reaction to an adjunct [(sic)]in the vaccine that . . . remain[ed] in the location of the injection." *Id.* Dr. Degenhardt prescribed anti-inflammatory cream to control these reactions. *Id.*

### B. Petitioner's Affidavit & Personal Office Visit Notes

On December 12, 2018, Petitioner filed an affidavit to provide testimony that she "would have offered" if "there been an evidentiary hearing . . . ." Pet'r's Aff. ¶ 2. In her affidavit, Petitioner noted that "immediately after [her] flu vaccination in October of 2014, [she] experienced respiratory tightness and visual disturbances and was unable to see out of both eyes." *Id.* at ¶ 2(a). She explained that these "symptoms resolved" quickly, but that "over the next few days, [she] began to experience tingling and numbness in [her] toes that quickly ascended up [her] left calf and both hands up to [her] elbows." *Id.* at ¶¶ 2(c)–(d). Petitioner stated that she reported these symptoms to her physician's office via telephone, because she "thought [she] had [GBS]." *Id.* at ¶ 2(e)–(f). However, her physician "dismissed [her] complaint[]" and told her that "if [she] had GBS[, she] would know it." *Id.* at ¶ 2(g). Petitioner was unable to obtain a record of this call,

[19] Cerebrospinal fluid is "[t]he fluid that flows in and around the hollow spaces of the brain and spinal cord, and between two of the meninges (the thin layers of tissue that cover and protect the brain and spinal cord)." CEREBROSPINAL FLUID, National Dictionary of Cancer Terms, National Cancer Institute (last visited Oct. 10, 2019), retrieved from https://www.cancer.gov/publications/dictionaries/cancer-terms/def/cerebrospinal-fluid.

because "the practice has been closed and sold twice." *Id.* at ¶ 2(h).

Petitioner further alleged that "[w]ithin [twenty-four] hours" of her Tdap vaccination on November 18, 2015, she "had a marked escalation and intensification of neurological symptoms: numbness, tingling, paresthesia in calves and forearms, left leg weakness, [and] severe pain at the right arm injection site . . . ." *Id.* at ¶ 2(t). She stated that she "returned to Dr. Preston within [forty-eight] hours" and "[h]e found abnormal findings on [a] neuro[logical] exam[] and made a referral to a neurologist." *Id.* at ¶ 2(u). However, Petitioner noted that "[i]t was difficult to obtain a timely neurological consult [because] the wait time was 8 months . . . ." *Id.* at ¶ 2(v). Instead, she "pursued a more timely appointment[,]" which she found with Dr. Stein on April 20, 2016. *Id.* at ¶ 2(w).

Petitioner stated that "given [her] experience with medical providers, as an R.N., and [c]ertified [c]linical [d]ocumentation [s]pecialist, [she is] a thorough historian with regard to [her] . . . medical appointments." *Id.* at ¶ 2(i). She explained that she "retain[ed] almost all of [her] office visit and diagnostic reports[] and compile[d] a written summary of [her] own recollection of what occur[ed] at the visits." *Id.* In addition, she stated that "for most of [her] doctor appointments since December 2014, [her] spouse (also an R.N.) accompanie[d her] into the exam room[] to act as a scribe to accurately record issues discussed during the visit." *Id.* She filed a copy of what she described as "notes of [her] primary care appointment on December 2, 2014."[20] *Id.* at ¶ 2(k); Pet'r's Ex. 10. The note is dated "12.2.14" and has "to Charles Burger" hand-written on the top. Pet'r's Ex. 10. The note describes "enormous physical sleep difficulties" because of "endless twitching, apnea, [and] heart irregularity" when Petitioner slept on her right side, as well as "pain deep inside [her] head through [her] [left] eardrum" when she slept on her left side. *Id.* The note also contains the following description of symptoms that Petitioner stated occurred after her flu shot:

> Since flu shot[,] [t]ingling, heart racing, weakness, apprehension. . . . waxing and waning, much less now. Unremitting anxiety with this . . . again, much better now. Episodic swallowing difficulty[.] Fingers and toes tingling; especially evident when I [am] awake, at times traveling up to forearms and shins. Toes feel like corks. Waxing and waning exacerbation of eyesight difficulties.

*Id.* Petitioner also wrote that she was "[c]onvinced [that] this is tied to [an] immune reaction . . . . triggered by allergens and stress." *Id.* Petitioner did not file a record of this December 2, 2014 office visit, because "the practice has been closed and sold twice" and she has therefore been unable "to obtain a record" of this appointment. Pet'r's Aff. ¶¶ 2(h), 2(j).

## III. Expert Review

[20] Although Petitioner did not file a record of this office visit, she did file medical records from an office visit with Dr. Burger that occurred on December 5, 2014. *See* Pet'r's Ex. 1(f) at 3. It is unclear if the December 2, 2014 visit Petitioner referenced in her affidavit and note actually occurred on December 5, 2014, or if she had appointments with Dr. Burger on both December 2nd and 5th of that year. However, there is no mention in the December 5, 2014 office records of a visit that occurred on December 2, 2014. *See id.*

### A. Petitioner's Expert, Alexandra Degenhardt, M.D., M.M.S.C.

Petitioner submitted three filings from Dr. Degenhardt, which she entitled "expert reports." *See* Pet'r's Exs. 3–4, 8, ECF Nos. 29-1, 33-1, 38-4. The first consisted of seven pages of medical records from an office visit Dr. Degenhardt had with Petitioner on June 5, 2018. *See* Pet'r's Ex. 3. Aside from these office notes, Dr. Degenhardt's first report did not provide any additional information regarding Petitioner's claim.

Petitioner submitted a second document from Dr. Degenhardt on October 2, 2018. Pet'r's Ex. 4. It consisted of a one-page letter which reads in full:

> [Petitioner] was seen by myself several times for symptoms that were most consistent with acute disseminated encephalomyelitis (ADEM) following vaccinations. ADEM can affect a discrete part, or multiple areas of the central nervous system, and at times portion[s] of the peripheral nervous system. Please see my office notes of 7/2016, 12/2016 and 2/2017 where Ms[.] Orloski's presentation and symtpoms (sic.) are detailed. I do not know if it is a[n] adjuvant in the vaccine that she is reacting to, as it occured (sic) after both a flu shot [on] 10/2014 and a tetanus shot [administered on] 11/2015, or if it is the actual superantigen. However, there is a clear temporal relationship between the vacciantions [(sic.)] and her symptoms, and so the most consistent diagnosis is ADEM.

*Id.* No additional information was provided.

Petitioner submitted Dr. Degenhardt's third and final filing on December 12, 2018. Pet'r's Ex. 8. It again consisted of a one-page letter which reads:

> As is commonly known in medicine and public health, vaccinations can cause [ADEM]. [Petitioner] clearly had reactions to her vaccinations and was seen by medical providers at the time. These specific dates were 10/23/2014 . . . and 11/18/15 . . . and she has documentation that she was seen by medical providers for reactions [to the vaccinations she received at those visits]. The neurological symptoms that I have seen [Petitioner] for [are] most consistent with recurrent symptoms of ADEM – mild left leg weakness, numbness on the left and mild cognitive issues. Her testing including CSF [were] supportive. She also saw another neurologist Dr. Reda at Mass General Hospital who agreed that the diagnosis was ADEM. [Petitioner] has documentation of that as well. Therefore, I . . . diagnosed [Petitioner] with ADEM as a reaction to her vaccinations.

*Id.* No additional information was provided.

### B. Respondent's Expert, Subramaniam Sriram, M.D.

Respondent submitted one expert report authored by Dr. Sriram on March 6, 2019, along with his curriculum vitae and one piece of supporting medical literature. Resp't's Exs. A–C, ECF Nos. 43-1–43-3. Dr. Sriram is a Professor of Neurology and Microbiology Immunology and head of the Multiple Sclerosis Clinic at the University of Vanderbilt Medical Center. Resp't's Ex. A at 1. He holds board certifications in Internal Medicine and Neurology. *Id.* He sees approximately 1,450 MS patients each year, of which 1,200 are in the outpatient setting and 250 are in the inpatient setting. *Id.* Dr. Sriram also conducts research on the causes and treatments of MS and "provide[s] consultation and care [for] patients with clinical features consistent with other demyelinating diseases of the [CNS]." *Id.*

Dr. Sriram opined that Petitioner's diagnosis is "uncertain." *Id.* at 4. He noted that "[t]he only objective finding [was] a mild left[-]sided weakness of uncertain etiology[,]" which "was first noted by Dr. Degenhardt on . . . July 14[,] 2016." *Id.* at 5. This symptom "was not apparent when Dr. Stein examined [Petitioner] on April 4[,] 2016." *Id.* Therefore, Dr. Sriram argued that the onset of weakness was likely subsequent to April of 2016, which was over sixteen months post-flu vaccination and six months post-Tdap vaccination. *Id.*

Dr. Sriram provided a table listing the criteria for the diagnosis of ADEM, which he created from an article by Krupp, Banwell, and Tenembaum. *Id.* (citing Resp't's Ex. C[21] at 1–2). On one side of the table, Dr. Sriram listed the following criteria used to diagnose ADEM: (1) "onset before the age of 10"; (2) "[a] first clinical event with a presumed inflammatory or demyelinating cause, with acute or subacute onset that affects multifocal areas of the CNS; the clinical presentation must be polysymptomatic and must include encephalopathy"; (3) "behavioral change occurs, e.g., confusion, excessive irritability, lethargy or coma"; and (4) "a mostly monophasic disease". *Id.* at 6 (emphasis in original). On the other side of the table, Dr. Sriram compared that criteria to Petitioner's presentation and argued that Petitioner did not meet any of the listed criteria: (1) "[Petitioner] was 58 years-old"; (2) Petitioner experienced "[n]o change in level of consciousness . . . and there was no encephalopathy"; (3) Petitioner did not exhibit any behavioral changes "at the time of diagnosis"; and (4) Petitioner's "symptoms have spanned more than three years." Therefore, Dr. Sriram "disagree[d] with the diagnosis of ADEM." *Id.* at 5.

Dr. Sriram argued that "[t]he [MRI] images are not consistent with a diagnosis of [a] CNS demyelinating disease, either acute (ADEM) or subacute chronic (MS)." *Id.* Dr. Sriram examined all of Petitioner's submitted brain and C-spine MRIs from the years 2008 to 2016 and concluded that "they do not show any progression of the punctuate lesions seen in the subcortical white matter." *Id.* He noted that "the conclusion of the [MRI] report state[d] that '[l]ow grade white matter disease present on May 5[,] 2016[,] [was] not significantly changed from 2009.'" *Id.* (quoting Pet'r's Ex. 1(c) at 9). Therefore, Dr. Sriram believed that they "are more likely patterns seen in patients with chronic migraine[s], which [Petitioner] suffered from." *Id.*

Dr. Sriram also argued that Petitioner's immediate visual symptoms after receiving the flu vaccine were "inconsistent with the time line necessary for the development of an autoimmune response." *Id.* at 6. He explained that ADEM "is a T cell[-]mediated autoimmune inflammatory demyelinating disease of the CNS." *Id.* Dr. Sriram wrote that "the accepted process for the

[21] Lauren B. Krupp, Brenda Banwell, and Silvia Tenembaum, *Consensus Definitions Proposed for Pediatric Multiple Sclerosis and Related Disorders*, 68 NEUROLOGY S2 (2007).

development of autoimmune demyelination[]" is the "recruitment, amplification[,] and migration of the autoimmune T cells to the brain" after an "immune sensitization in the peripheral lymphoid organs[.]" *Id.* Therefore, Dr. Sriram opined that "[t]he pre-requisite[ timeframe] for T cell activation and migration to the CNS [is] 7–10 days." *Id.* He argued that "[i]f the vaccine [induced] the autoimmune response, it is unlikely that a neurological event [could] occur within one hour of the receipt of the vaccine[,]" and "it is also very unlikely that the autoimmune response [would] resolve in a matter of hours." *Id.* Therefore, Dr. Sriram concluded that it was his "opinion and to a fair degree of medical certainty that the neurological symptoms suffered by [Petitioner] were not related to the receipt of her flu or Tdap vaccine[s]." *Id.* at 7.

## IV. Petitioner's Motion for a Ruling on the Record

Petitioner filed her motion for a ruling on the record on December 12, 2018. ECF No. 37. Petitioner conceded in her motion that "she ha[d] not submitted a hired expert opinion explaining the exact biological mechanism as to how vaccinations can cause ADEM." *Id.* at 7. However, Petitioner argued that an expert opinion of that kind is unnecessary because her immediate symptom onset, Dr. Degenhardt's opinion, and submitted medical literature are "sufficient to meet Petitioner's burden to establish prong one of *Althen*." *Id.* at 8.

Specifically, Petitioner stated that "[m]edical and scientific literature, case studies, and case reports suggest that a wide variety of inflammatory diseases temporally associated with the administration of various vaccines, have been reported in the literature." *Id.* at 9 (citing Pet'r's Ex. 6 at 1). Petitioner submitted two pieces of medical literature in support of her motion. *See* Pet'r's Exs. 6, 9, ECF Nos. 38-1, 38-5. The first is authored by Karussis and Petrou.[22] In the introduction, the authors state that "[t]he vast majority of post-vaccination CNS demyelinating syndromes[] are related to the [flu] vaccination[,]" although they explained that "this could be attributed to the high percentage of the population that received the vaccine . . . ." Pet'r's Ex. 6 at 1. The authors explained that "[u]sually the symptoms of the CNS demyelinating syndrome appear [a] few days following the immunization (mean: 14.2 days)[,] but there are cases where the clinical presentation was delayed (more than [three] weeks or even up to [five] months post-vaccination)." *Id.*

The authors provided a brief overview of post-vaccination ADEM. *Id.* at 2–3. They wrote that "ADEM can occur in any age but is mainly a disease of children and young adults[,] with a mean age of onset of [five]–[six] years[,] and [the disease has] a higher incidence in males." *Id.* at 2. They also explain that, while "[t]he clinical presentation [of ADEM] . . . is widely variable," "[e]ncephalopathy, [which] occur[s] in up to [seventy-four percent] of patients, is considered mandatory for a definitive diagnosis." *Id.* The authors list the varicella, rubella, smallpox, and flu vaccines as "common causes of post-vaccination ADEM."

The authors also provide two hypotheses for how vaccination can cause ADEM. The first is molecular mimicry where "antigens of viral origin cross-react with myelin components . . . and in a secondary manner induce a hyperergic reaction[] that leads to the development of disseminated demyelination." *Id.* The second is T-cell activation where "vaccination may activate in a non-

[22] Dimitrios Karussis & Panayiota Petrou, *The Spectrum of Post-vaccination Inflammatory CNS Demyelinating Syndromes*, AUTOIMMUNITY REV. (2013).

specific way distinct clones of anti-myelin T cells and that suppressor or regulatory cells that are aimed to control this abnormal reactivity are compromised or malfunctioning." *Id.* The authors did not make a determination on the viability of either hypothesis. *See id.*

The second article, authored by Yuan et al.,[23] is a case report describing a twelve-year-old child who developed ADEM after receiving the Hepatitis B virus ("HBV") vaccine. Pet'r's Ex. 9 at 1. The only mention in this article of the vaccines Petitioner received is as follows: "Post[-]vaccination ADEM has been associated with several vaccines such as . . . [the Tdap] . . . [and flu] . . . vaccine[s]." *Id.* at 2–3.

Petitioner further argues that "there are numerous instances in the Vaccine Program in which . . . petitioner[s] ha[ve] established a plausible causation theory, including the plausibility of different vaccines, including the flu vaccine to cause ADEM or similar [CNS] neurological injuries." *Id.* at 10 (quoting *Taylor v. Sec'y of Health and Human Servs.*, No. 13-700V, 2018 WL 2050857, at *23 (Fed. Cl. Spec. Mstr. Mar 9, 2018). Petitioner also cites to another Vaccine Program case, *Caruso v. Sec'y of Health and Human Services*, No. 15-200V, 2017 WL 5381154, at *14 (Fed. Cl. Spec. Mstr. Oct. 18, 2017), for the proposition that "there is ample existing [Vaccine] Program authority (backed up by reliable scientific and medical evidence) that certain vaccines, including the flu vaccine, are reasonably associated with ADEM." Petitioner concluded that "[i]n most of the cases in which the Court has denied ADEM claims, it is because a petitioner has failed to establish prong two or three of *Althen*, not one." ECF No. 37 at 11.

To establish *Althen* prongs two and three, Petitioner argues that "the medical records . . . clearly support [her] claim that she became immediately ill after receipt of the flu vaccination and then again immediately following the Tdap vaccination." *Id.* Therefore, Petitioner continues, "[g]iven the immediate onset of symptoms not once, but twice, the records could not more clearly establish a temporal link to reactions to both vaccinations." *Id.* However, Petitioner claims that if the medical records are "not enough to meet Petitioner's burden in this matter, her treating neurologist[] Dr. Degenhardt has opined that Petitioner's injuries are likely the result of reactions to both the [flu] and Tdap vaccinations." *Id.* at 12.

## V. The Applicable Legal Standard

To receive compensation under the Vaccine Act, Petitioner must demonstrate either that: (1) she suffered a "Table injury" by receiving a covered vaccine and subsequently developing a listed injury within the time frame prescribed by the Vaccine Injury Table set forth at 42 U.S.C. § 300aa-14, as amended by 42 C.F.R. § 100.3; or (2) that she suffered an "off-Table injury," one not listed on the Table as a result of her receipt of a covered vaccine. *See* 42 U.S.C. §§ 300aa-11(c)(1)(C); *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1319-20 (Fed. Cir. 2006). Petitioner does not allege a Table injury in this case; thus, she must prove that her injury was caused-in-fact by a Table vaccine.

[23] Jun-liang Yuan et al., *Acute Disseminated Encephalomyelitis Following Vaccination Against Hepatitis B in a Child: A Case Report and Literature Review*, CASE REPORTS IN NEUROLOGICAL MEDICINE (2016).

To establish causation-in-fact, Petitioner must demonstrate by a preponderance of the evidence that the vaccine was the cause of the injury. 42 U.S.C. § 300aa-13(a)(1)(A). Petitioner is required to prove that the vaccine was "not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321–22 (quoting *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)).

In the seminal case of *Althen v. Secretary of the Department of Health and Human Services*, the Federal Circuit set forth a three-pronged test used to determine whether a petitioner has established a causal link between a vaccine and the claimed injury. *See* 418 F.3d 1274, 1278–79 (Fed. Cir. 2005). The *Althen* test requires the petitioner to set forth: "(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury." *Id.* at 1278. To establish entitlement to compensation under the Program, Petitioner is required to establish each of the three prongs of *Althen* by a preponderance of the evidence. *See id.*

Under the first *Althen* prong, Petitioner must offer a scientific or medical theory that answers in the affirmative the question "can the vaccine[] at issue cause the type of injury alleged?" *See Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff'd*, 64 Fed. Cl. 19 (2005), *aff'd*, 451 F.3d 1352 (Fed. Cir. 2006). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 548–49. However, as the Federal Circuit has made clear, "simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." *LaLonde v. Sec'y of Health and Human Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) (citing *Moberly*, 592 F.3d at 1322). Rather, "the statutory standard of preponderance of the evidence requires a petitioner to demonstrate that the vaccine more likely than not caused the condition alleged." *Id.*

A petitioner is not required to present medical literature or epidemiological studies to prove her burden. *Grant v. Sec'y of Health and Human Servs.*, 956 F.2d 1144, 1149 (Fed. Cir. 1992); *Andreu v. Sec'y Health & Human Servs.*, 569 F.3d 1367, 1380 (Fed. Cir. 2009). However, to the extent medical literature and epidemiological studies are provided, the special master will consider them when deciding whether the petitioner has met her burden of proof. Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Andreu*, 569 F.3d at 1380. But this does not negate or reduce a petitioner's ultimate burden to establish his overall entitlement to damages by preponderant evidence. *W.C. v. Sec'y of Health & Human Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted).

Under *Althen*'s second prong, petitioners must demonstrate that the vaccine actually did cause the alleged injury in a particular case. *See Pafford*, 2004 WL 1717359, at *4; *Althen*, 418 F.3d at 1279. The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278;

*Andreu*, 569 F.3d at 1380; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Health Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). A petitioner does not meet this obligation by showing only a temporal association between the vaccination and the injury; instead, the petitioner "must explain how and why the injury occurred." *Pafford*, 2004 WL 1717359, at *4 (emphasis in original).

In Program cases, contemporaneous medical records and the opinions of treating physicians are favored. *Capizzano*, 440 F.3d at 1326 (citing Althen, 418F.3d at 1280). This is because "treating physicians are likely to be in the best position to determine whether 'a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury.'" *Id.* In addition, "[m]edical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health and Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). While a special master must consider these opinions and records, they are not "binding on the special master or court." 42 U.S.C. § 300aa-13(b)(1). Rather, when "evaluating the weight to be afforded to any such . . . [evidence], the special master . . . shall consider the entire record . . . ." *Id.*

Under the third prong of *Althen*, a petitioner must show that the timing of the injury fits with the causal theory. *See Althen*, 418 F.3d at 1278. For example, if the petitioner's theory involves a process that takes several days to develop after vaccination, an injury that occurred within a day of vaccination would not be temporally consistent with that theory. Conversely, if the theory is one that anticipates a rapid development of a reaction post-vaccination, the development of the alleged injury weeks or months post vaccination would not be consistent with that theory. Causation-in-fact cannot be inferred from temporal proximity alone. *See Grant*, 956 F.2d at 1148; *Thibaudeau v. Sec'y of Health & Human Servs.*, 24 Cl. Ct. 400, 403–04 (1991); *see also Hasler v. United States*, 718 F.2d 202, 205 (6th Cir. 1983) ("Without more, [a] proximate temporal relationship will not support a finding of causation.").

## VI. Discussion

### A. *Althen* Prong One

Petitioner failed to meet her burden under *Althen* prong one. As Petitioner acknowledges, "she has not submitted a hired expert opinion explaining the exact biological mechanism as to how vaccinations[24] can cause ADEM." Pet'r's Mot. for Ruling on the Rec. at 7. Petitioner argues instead "that no such opinion is necessary[,] because" the evidence she submitted is enough to meet her burden. She cites to the following evidence to satisfy *Althen* prong one: (1) Dr. Degenhardt's opinion that the vaccinations caused her alleged ADEM; (2) the medical literature contained in the record; and (3) her immediate onset after receiving both vaccinations. None of

[24] Petitioner mistakes the burden that she must meet under *Althen* prong one. Her burden is not to show that *any* vaccination could cause ADEM, but rather that the flu and/or Tdap vaccines could cause ADEM. Furthermore, Petitioner does not necessarily have to provide the specific biological mechanism of a causation theory. She must, however, identify a "sound and reliable medical" theory relevant to her vaccination and alleged condition. *Knudsen*, 35 F.3d at 548.

these, whether taken separately or in the aggregate, are sufficient to meet the preponderant standard.

Dr. Degenhardt's assertions do not provide preponderant evidence under *Althen* prong one for numerous reasons. First, her assertions are superficial. Dr. Degenhardt did not present a theory of causation to apply to Petitioner's case. After a thorough reading of her "expert reports," it is unclear which vaccination Dr. Degenhardt believes caused Petitioner's ADEM, or if she believes it was both. Nowhere in Dr. Degenhardt's reports did she discuss a mechanism for how the Tdap vaccine or the flu vaccine—or a combination of both—could cause ADEM. She did not discuss what an appropriate temporal relationship would be for the flu or Tdap vaccines to be linked to the development of ADEM. She also did not discuss ADEM's relationship to the wild viruses that Petitioner's vaccines protect against. And although not a requirement, Dr. Degenhardt did not cite to any medical literature or epidemiological studies to support her contention that these vaccines can cause ADEM.

Furthermore, Dr. Degenhardt's assertions are afforded substantially less weight because, notwithstanding her role as a treating neurologist, she did not provide her qualifications to opine on Petitioner's case. Dr. Degenhardt did not file a curriculum vitae or résumé. She did not state whether she is board-certified in immunology, neurology, or any other area that is pertinent to Petitioner's claim. It is unclear whether Dr. Degenhardt has published any articles discussing issues pertinent to Petitioner's case in peer-reviewed journals or whether she has testified in any medico-legal matters. It is also unclear whether Dr. Degenhardt holds any research or academic positions outside of her neurological practice or has any experience treating patients with ADEM. Without this information, it is difficult to assess the authority and reliability of Dr. Degenhardt's conclusions.

Petitioner had numerous opportunities to provide information in support of Dr. Degenhardt's conclusions. *See* ECF Nos. 32, 34. On October 22, 2018, I gave Petitioner detailed instructions on what information she should include in her expert reports. *See* ECF No. 32. After Petitioner submitted Dr. Degenhardt's second report on October 15, 2018, I alerted her that the filing did not comply with my instructions, and I gave her an additional opportunity to submit a proper expert report. *See* ECF No. 34. Despite these opportunities, Petitioner failed to adequately support Dr. Degenhardt's assertions. Therefore, her opinions and reports are not persuasive evidence to meet Petitioner's burden under *Althen* prong one.

Although she was not required to submit medical articles in support of her claim, *see Andrue*, 569 F.3d at 1380, Petitioner argues that the two articles she submitted along with her motion for a ruling on the record support her argument under *Althen* prong one. These articles are also insufficient, however, to meet Petitioner's burden, because they do not specifically address how the vaccines Petitioner received can cause her alleged injury. While the Karussis and Petrou article does briefly discuss molecular mimicry and T cell activation, two theories widely considered to explain vaccine-induced ADEM, the authors do not conclude whether either hypothesis is viable. Petitioner also did not identify which theory from this article she is advancing in this case. In addition, although the authors list the flu vaccine as a "common cause[] of post-vaccination ADEM[,]" it is unclear how this statement comports with another statement in the article that "despite a close temporal relation[hip] to vaccinations, there is no concrete evidence of

a clear pathogenic correlation" between vaccinations and ADEM." Pet'r's Ex. 6 at 3. The Yuan et al. article is a case report documenting a twelve-year-old child's development of ADEM after receiving the HBV vaccine. Petitioner never attempts to explain how the HBV vaccine is analogous to either the flu or Tdap vaccines. She also did not discuss how the characteristics of the child in the case report—a twelve-year-old male—is analogous to her characteristics—a fifty-eight-year-old female. The child in this case report also has a confirmed ADEM diagnosis, whereas Petitioner diagnosis is differential at best. Therefore, these pieces of medical literature are not persuasive evidence to meet Petitioner's burden under *Althen* prong one.

Lastly, Petitioner argues that her immediate onset of symptoms after both the flu and Tdap vaccinations is supportive of a finding under *Althen* prong one. However, without additional preponderant evidence, this argument is misplaced. Petitioner is correct that evidence used to establish one *Althen* prong may be used to satisfy another. *See Cappizano*, 440 F.3d at 1326. However, the Court has stated that "a proximate temporal association alone does not suffice to show a causal link between the vaccination and the injury." *Grant*, 956 F.2d at 1148. Therefore, the onset of Petitioner's symptoms taken with her other filings cannot meet her burden under prong one. Importantly, Petitioner has not articulated an appropriate temporal association under her causation theory. In fact, one of the articles she submitted proposed a timeframe of approximately two weeks for symptom development post vaccination. The authors also described cases where onset occurred later than this period. Petitioner did not explain why her alleged immediate onset of symptoms is medically acceptable, how it is consistent with her filed literature, or how it supports her argument under this prong. Therefore, this evidence is insufficient to meet her burden under prong one.

For these reasons, Petitioner has failed to meet her burden under *Althen* prong one.

**B. *Althen* Prong Two**

Petitioner cannot meet her burden under *Althen* prong two, because she did not provide a causation theory under prong one to apply to her symptoms. Furthermore, she did not establish a logical sequence of cause and effect, supported by her medical records, to show that her vaccinations actually caused her alleged ADEM. Aside from Dr. Degenhardt's unsupported assertions, Petitioner only argues that the temporal onset of her ADEM symptoms supports *Althen* prong two.

The parties dispute, however, whether Petitioner's ADEM diagnosis is definitive, and Petitioner has not provided preponderant evidence that she suffers from this condition. Dr. Degenhardt's diagnosis is differential, and she did not support her diagnosis with a discussion of the medical records. Aside from conclusory statements and superficial citations to records from her office visits with Petitioner, Dr. Degenhardt's filings do not adequately explain why she believed Petitioner suffered from ADEM nor what criteria she used to diagnose Petitioner with ADEM. While Dr. Degenhardt referred to "neuropsychology testing" in Petitioner's medical records, she did not provide any explanation for how she used this type of testing to assess Petitioner with ADEM. The National Institute of Health characterizes this type of testing as a behavioral assessment used to diagnose mental illness. *See* Court's Ex. A at 1. Dr. Degenhardt did not provide any medical literature to show that neuropsychological testing can be used to

diagnose a neurological disorder. Dr. Degenhardt also did not discuss the opinions of two of Petitioner's other treaters, Dr. Reda and Dr. Preston, nor the opinion of Respondent's expert, Dr. Sriram, none of whom diagnosed Petitioner with ADEM.

Petitioner is correct that opinions of treating physicians are afforded significant consideration by the Court. Pet'r's Mot. for Ruling on the Record at 12. However, I must consider the entire record when assessing a treating physician's opinion. *Cucuras*, 993 F.2d at 1528. When taking the entire record into account, Dr. Degenhardt's opinion that Petitioner was suffering from vaccine-induced ADEM is not persuasive. Petitioner saw multiple treaters with differing opinions. Dr. Preston concluded that most of Petitioner's symptoms related to her longstanding anxiety, *see* Pet'r's Ex. 1(b) at 66, while Dr. Reda concluded that Petitioner's diagnosis was more likely MS based off neuroimaging grounds, not ADEM, *see* Pet'r's Ex. 1(b) at 45. Taken in total, these results are indeterminate, but it is noteworthy that Dr. Degenhardt provides the least support for her conclusions. In fact, while Dr. Sriram did not provide an explanation for Petitioner's symptoms, he also discussed Petitioner's record, and he used medical literature to support his conclusions. Dr. Sriram provided a chart contrasting Petitioner's presentation with the criteria for diagnosing ADEM and concluded that Petitioner did not meet any of the listed criteria. *See* Resp't's Ex. A at 5. Petitioner did not disagree with the diagnostic criteria nor provide evidence that she met any of the listed criteria.

Furthermore, Petitioner's own medical literature contradicts her alleged ADEM diagnosis. The article by Karussis and Petrou explains that encephalopathy "is considered mandatory for a definitive [ADEM] diagnosis." Pet'r's Ex. 6 at 2. Petitioner provided no evidence that she developed an encephalopathy, and Dr. Degenhardt did not explain how she made an ADEM diagnosis in the absence of this finding. For those reasons, I find that Petitioner has not provided preponderant evidence that she suffers from ADEM or that her symptoms were caused by her vaccines. Therefore, Petitioner has not met her burden under *Althen* prong two.

### C. *Althen* Prong Three

It is difficult to ascertain whether there was an appropriate temporal relationship between Petitioner's vaccines and her alleged injury, because neither Petitioner nor Dr. Degenhardt clearly defined the applicable onset window. Petitioner argues that her immediate onset is evidence of an appropriate temporal relationship. However, the article by Karussis and Petrou places the appropriate symptom onset for CNS demyelinating disorders at days, with a mean symptom onset of two weeks. Pet'r's Ex. 6 at 1. Petitioner did not provide an explanation for why the temporal relationship discussed in this article is wrong or provide any support to show that her immediate onset is appropriate.

Furthermore, Dr. Sriram's expert report provides persuasive evidence that Petitioner's symptom onset is inconsistent with vaccine-induced ADEM under any causation theory. Dr. Sriram argued that vaccine-induced ADEM would require at least seven-to-ten days from the date of vaccination to develop. Resp't's Ex. A at 6. Although Dr. Sriram did not provide medical literature directly supporting this contention, his impressive credentials make him credible on this topic. As a professor of neurology and immunology and head of the MS Clinic at Vanderbilt University Medical Center, he is qualified to opine on an appropriate temporal relationship in this

case. Petitioner did not provide any evidence to refute this timeframe, either through Dr. Degenhardt's reports or additional medical literature.

I find Petitioner's filed medical literature and Dr. Sriram persuasive. I therefore find that Petitioner did not establish with preponderant evidence that she developed vaccine-induced ADEM after she received her flu and Tdap vaccines. Accordingly, Petitioner has not met her burden under *Althen* prong three.

## VII. Conclusion

For the foregoing reasons, Petitioner's claim is hereby DISMISSED for insufficient proof. The Clerk of Court is directed to enter judgment accordingly.[25]

**IT IS SO ORDERED.**

s/Herbrina D. Sanders
Herbrina D. Sanders
Special Master

[25] Pursuant to Vaccine Rule 11(a), entry of judgment is expedited by the parties' joint filing of a notice renouncing the right to seek review.